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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,892	09/30/2003	Michael John Reed	674519-2011.1	4836

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FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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07/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/674,892

Applicant(s)

REED ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7,9-32 and 65 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,9-32 and 65 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

2. The objection to the disclosure is withdrawn.

Claim Rejections - 35 USC § 112

3. The rejection of claim 65 under 35 USC 112, first paragraph is withdrawn.
4. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The structure of formula VII is incomplete and, thus, the instant claim is indefinite.

Double Patenting

5. The rejections of claims 1-3, 5-7, 9-32 and 65 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent Nos. 5,830,886; 5,616,574 and 5,604,215 are withdrawn.

6. The rejections of claims 1-3, 5-7, 9-32 and 65 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent Nos. 6,903,084 and 7,119,081(US Application No. 10/955,962) and the provisional rejection of the instant claims over claims of US Application No. 10/367,114 as well as patents and applications listed in paragraph 15 of Office Action dated May 17, 2006 are maintained.

Applicant argues that even if the claims are read in view of the specification, the double patenting rejection should be withdrawn because the cited references do not teach compounds wherein at least one of the 2- and 4-position is substituted with other than hydrogen. Applicant also argues the recitation of specific 2-substituted nucleuses by the claims of the cited reference is not enough to maintain the rejection because of a showing of unexpected results. Applicant's argument was considered but not persuasive for the following reasons.

Each of the cited patent and copending application encompasses 2- and/or 4-substituted sulphamate steroid derivatives either by specific recitation in the instant claims or teaching of specific compounds in the disclosure. For example, '084, claim 1 recites 2-OH estrone, 2-methoxy estrone etc.; '081, claims 1-11 are drawn to 2-substituted-3,17-disulphamate steroids; '597, claim 1 recites 2-halo-3-sulphamate estrone derivatives; '934, claim 14 recites 2-methoxyestrone-3-sulphamate etc. Thus, applicant's argument that the references do not teach the claimed compounds is not persuasive.

As discussed above, the references exemplify substitution of 3-sulphamates derivatives in the 2- and/or 4-positions of the steroid moiety. The instant claims

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encompass every 2- and/or 4-substituted sulphamate steroid derivatives and, thus, is inclusive of those recited by the instant claims. Applicant's argument of unexpected results does not obviate the instantly claimed compounds encompassed by the cited references. The examiner notes that said showing overcomes prior art rejection but does not overcome the double patenting rejection based on the above-cited references.

For these reasons and those given in the previous Office Actions, the rejections of claims 1-3, 5-7, 9-32 and 65 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent Nos. 6,903,084 and 7,119,081(US Application No. 10/955,962) and the provisional rejection of the instant claims over claims of US Application No. 10/367,114 as well as patents and applications listed in paragraph 15 of Office Action dated May 17, 2006 are maintained.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
June 27, 2007